IMPROVING ADHERENCE TO MEDICATION REGIMENS FOR CHILDREN WITH ASTHMA AND ITS EFFECT ON CLINICAL OUTCOME

Irene G. da Costa university of kansas

MICHAEL A. RAPOFF

UNIVERSITY OF KANSAS MEDICAL CENTER

KATHLEEN LEMANEK
UNIVERSITY OF KANSAS

AND

GERALD L. GOLDSTEIN

KANSAS CITY ALLERGY AND ASTHMA ASSOCIATES,
OVERLAND PARK, KANSAS

We examined the effects of a combined education and token system intervention to improve adherence to inhaled corticosteroids for an 8-year-old girl and a 10-year-old boy with asthma. Adherence was measured by an electronic chronolog monitor, and disease outcome was assessed by repeated pulmonary function testing. A withdrawal design demonstrated improved adherence and, for 1 child, an associated improvement in pulmonary function occurred. Methodological and clinical implications are discussed, including variables other than adherence that may affect disease outcome.

DESCRIPTORS: compliance, asthma, medications, token system, disease activity

Despite advances in pharmacological treatments, hospitalization and mortality rates among children with asthma are on the rise. One explanation for this increase is medication nonadherence, which ranges from 17% to 90% for children with asthma (Lemanek, 1990). In spite of the prevalence and potentially serious consequences of nonadherence to asthma medications, few

This study is based on a master's thesis submitted by the first author to the Department of Psychology, University of Kansas. An extended version of this manuscript and a copy of the token system handout used in this study are available from the second author.

Address correspondence and requests for reprints to Michael Rapoff, University of Kansas Medical Center, Department of Pediatrics, 3901 Rainbow Blvd., Kansas City, Kansas 66160-7330 (E-mail: MRapoff@kumc.edu).

studies have evaluated strategies for improving adherence. Those that have done so failed to include proper experimental controls, relied on global ratings of adherence, did not collect repeated and long-term follow-up data on adherence and treatment outcome, or targeted adherence to medications (e.g., theophylline) that are no longer the mainstay of asthma treatment (Rapoff & Barnard, 1991). This pilot study attempted to address these methodological deficiencies and demonstrate the effectiveness of a combined education and token system intervention in improving adherence and pulmonary function for 2 children who had been identified by their referring allergist as being nonadherent to their asthma medications.

METHOD

Participants

Participants were 2 children with asthma, Annie, an 8-year-old girl, and John, a 10-year-old boy, who were referred by a board-certified allergist at a private practice clinic because of poor adherence to their medication regimens. Annie's primary medication regimen consisted of three puffs of beclomethasone (an inhaled corticosteroid) to be taken three times a day. John's primary medication regimen consisted of three puffs of beclomethasone to be taken twice daily.

Measures

Adherence was assessed with a chronolog (Medtrac Technologies), an electronic monitor that records and stores the date and time of each inhaler actuation. Data were downloaded during weekly home visits, and adherence percentage rates were calculated by dividing the number of actuations recorded each day by the number of actuations prescribed and multiplying by 100%. Reliability of the chronolog was assessed by testing and calibrating prior to baseline and recalibrating after downloading data. Pulmonary function was assessed once during each phase of the study by a nurse using a spirometer, an objective measure of lung volume and flow rates (Allen, 1994). Treatment integrity was assessed by comparing parents' daily records of awarding points and privileges with the chronolog data. These data are summarized by computing a percentage of the intervention days when parents correctly implemented the intervention. Treatment acceptability was assessed at the end of the study by asking parents and children to rate how helpful the program was to them using a Likert-type scale ($1 = not \ very \ helpful \ to \ 5$ = very helpful).

Design and Procedure

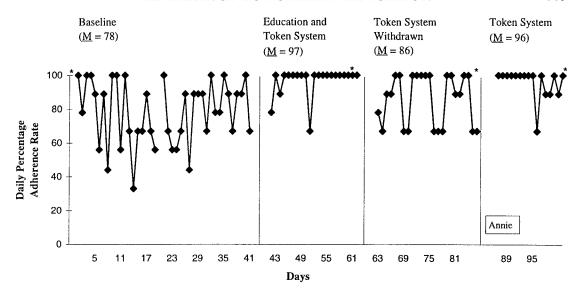
A withdrawal design was used to assess the effect of the intervention on adherence.

The intervention included asthma education and a token system. During a single 2-hr session, parent and child viewed videos and reviewed written handouts that addressed the topics of normal pulmonary functioning, asthma pathophysiology, medications, triggers, and management of asthma episodes. The token system involved the children earning points for taking their medications, exchanging points for privileges, and a loss of privileges for 1 day when they failed to take medications. The token system was withdrawn and then reintroduced for Annie, but John's mother declined to reintroduce the program because she likened the program to "bribery." Also, because of their busy schedules and a back injury to Annie that required surgery, she and her mother declined to participate in the follow-up assessments. Thus, 3-month, 6-month, and 14-month follow-up measures of adherence and pulmonary functioning were collected only for John.

RESULTS AND DISCUSSION

Adherence and Pulmonary Function

As is shown in Figure 1, both Annie's and John's adherence rates were variable during baseline, increased during the initial intervention phase, and decreased (although not to baseline levels) when the token system was withdrawn. Annie's adherence improved when the token system was reintroduced, and John's adherence decreased over followup. These data are consistent with the extant (but limited) literature which shows that behavioral programs, such as token systems, are necessary additions to educational programs for improving adherence to treatment regimens for children's chronic diseases (Lemanek, 1990; Rapoff & Barnard, 1991). However, these conclusions are tentative, given the modest results with John and the lack of follow-up data for Annie.



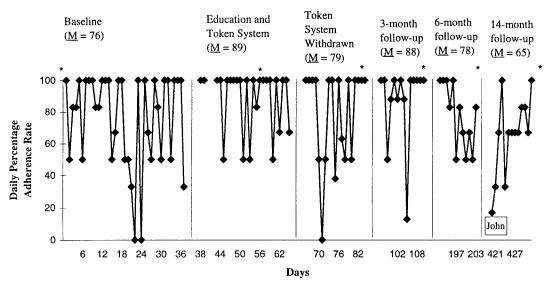


Figure 1. Daily percentage adherence rates to inhaled corticosteroids in the treatment of asthma for Annie (top graph) and John (bottom graph) as measured by an electronic monitor. * = pulmonary function testing occasions.

Also, the results are tempered by how adherence was assessed. Electronic monitors are considered to be state of the art in adherence assessment, but patients may trigger the device without ingesting the medication. Additional adherence measures (such as assays or direct observations) are needed to as-

sess the convergent validity of electronic monitors (Rapoff & Barnard, 1991).

The spirometry measures of pulmonary functioning for each child are displayed in Table 1. Although there were some clinically significant improvements in pulmonary function for Annie during the first interven-

Table 1 Pulmonary Function Results Obtained by Study Phase

| Phase | FVC | FEV ₁ | MMEF |
|----------------------------|------|------------------|------|
| Annie | | | |
| Baseline | 79% | 82% | 102% |
| Education and token system | 94% | 98% | 130% |
| Token system withdrawn | 97% | 100% | 125% |
| Token system | 110% | 111% | 132% |
| John | | | |
| Baseline | 84% | 74% | 64% |
| Education and token system | 96% | 81% | 64% |
| Token system withdrawn | 91% | 78% | 64% |
| 3-month follow-up | 77% | 71% | 68% |
| 6-month follow-up | 93% | 83% | 75% |
| 14-month follow-up | 97% | 85% | 74% |

Note. FVC = forced vital capacity, the total volume of air expired as rapidly as possible; FEV_1 = forced expiratory volume—one second, the volume of air expired in 1 s from maximum inspiration; and MMEF = maximum midexpiratory flow rate, the slope of the line between 25% and 75% of the forced expiratory volume. Values represent a percentage of predicted normal ranges, based on the child's age and height. Values in boldface represent a clinically significant change (+10%) relative to baseline levels (for both children in the first intervention phase) and relative to the withdrawal phase (for Annie when the token system was reintroduced).

tion phase, these values did not reverse when the token system was withdrawn, and John showed few changes, thus mitigating conclusions that the intervention produced reliable health benefits for these children. This is also consistent with the extant literature that raises doubts about the veridical relationship between adherence and disease outcomes (Rapoff & Barnard, 1991). Ceiling effects may have attenuated improvements, in that the children in this study had relatively high baseline pulmonary function. Also, we did not assess adherence to other asthma treatment components, such as inhaled bronchodilator medications or environmental control measures (e.g., reducing exposure to indoor allergens and irritants) that affect pulmonary function. Future studies should recruit children with low adherence and compromised pulmonary function (because they are likely to acquire health benefits from improved adherence) and should assess

and specifically target adherence to all treatment recommendations.

Treatment Integrity and Acceptability

Mothers of both children correctly awarded points on 75% or more of the days the token system was in effect. On all but one occasion, errors consisted of awarding maximum points on days when adherence was below 100%. Treatment acceptability ratings by children and parents were 5 (very helpful) with the exception of Annie, whose rating was 4.5 (between helpful and very helpful). There is a discrepancy between the high approval rating from John's mother and her reason for not reimplementing the token system ("it's bribery"). We can only speculate about this discrepancy. One possibility is that the global nature of the acceptability rating (along the dimension of overall helpfulness of the intervention) did not capture ratings specific to the acceptability of the token system.

Despite the limitations and modest outcomes, this study is the first (to our knowledge) to utilize the chronolog measure to assess adherence to inhaled corticosteroids in an adherence intervention trial. Also, very few studies have attempted to improve adherence while repeatedly assessing potential health benefits, such as improved pulmonary function.

From a clinical perspective, the token system used in this study is promising and efficient, making it feasible for use in pediatric subspecialty clinics. But, some parents (like John's in this study) object to using extrinsic rewards. One way to address this issue is by verbally framing reinforcement-based programs as temporary motivational operations that can increase adherence to the point that improvements in disease symptoms accrue and serve as intrinsic or natural reinforcers for continued adherence. However, this study suggests that improvements in disease symptoms may be modest in spite of in-

creased adherence. This suggests that more powerful medical treatments may be required to improve symptoms and thereby maintain adherence.

REFERENCES

Allen, J. L. (1994). Office pulmonary function testing. In D. V. Schidlow & D. S. Smith (Eds.), *A practical guide to pediatric respiratory diseases* (pp. 281–288). Philadelphia: Hanley & Belfus.

Lemanek, K. (1990). Adherence issues in the medical management of asthma. *Journal of Pediatric Psychology*, 15, 437–458.

Rapoff, M. A., & Barnard, M. U. (1991). Compliance with pediatric medical regimens. In J. A. Cramer & B. Spiker (Eds.), *Patient compliance in medical practice and clinical trials* (pp. 73–98). New York: Raven Press.

Received March 3, 1997 Initial editorial decision April 5, 1997 Final acceptance July 22, 1997 Action Editor, Patrick C. Friman